K132087

510(k) Summary of Safety and Effectiveness for Update to PercuNav

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21 CFR. Part 807.92.

I. Manufacturer/Owner

Manufacturer's Name
Philips Healthcare.
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JUL 2 4 2013

II. Contact Person

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III. Propriety Name/Classification Name

Propriety Name:	PercuNav
Common Name:	Computer assisted, image-guided surgery system
Classification Name:	Computed Tomography X-ray System Class II as described in 21 CFR 892.1750
Product Code:	JAK

IV. Date Prepared

April 01, 2013

V. Device Description

The PercuNav system provides image guided intervention and diagnostic information which guides interventional instrumentation to targets that have been defined by the physician. The target can be indicated either pre-procedurally or intra-procedurally using images or relative to an indicated position on the patient. As a diagnostic system, it combines pre-procedural and intra-procedural imaging to assist in locating areas of interest detected on one set of images on the other. The system provides fusion between different modalities. Different imaging modalities such as CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various

combinations, for example CT with MR, CT with Ultrasound, PET/CT with ultrasound, MR with ultrasound, etc.

VI. Purpose of Submission

Philips Healthcare is submitting this Special 510(k) to address modifications to the Ultrasound Tracker accessory. When used together with the PercuNav system, the Ultrasound Tracker device provides electromagnetic (EM) tracking of an ultrasound transducer in a varying EM field, and displays the transducer's real-time position in the PercuNav system. The Ultrasound Tracker Tracker attaches to a mounting plate or equivalent mating surface on the transducer or transducer bracket.

The Philips PercuNav Ultrasound Tracker is designed to be used with the PercuNav image-guided intervention system for diagnostic or interventional procedures using ultrasound. The Ultrasound Tracker consists of a connector, a cable, and tracked-sensor housing with a release tab that attaches to the needle-guidance system.

Modifications were made to the PercuNav Ultrasound tracker accessory which focuses mainly on durability of the product. The currently released PercuNav accessory is provided as single use devices and sterile. This has been challenged by many customers who feel that these trackers should be reusable and also do not need to be sterile as the only come into contact with the intact skin of the patient (i.e. non-critical medical device as per *Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on May 2, 2011).*

The modifications described in this Special 510(k) have not altered the basic fundamental technology of the predicate PercuNav Ultrasound tracker K121498. The modified Ultrasound tracker has the same technological characteristics as the legally marketed predicate device with exception that this new tracker is provided non – sterile and intended undergo cleaning and disinfection reprocessing at the hospital facility.

VII. Description of Device Modification

Philips Healthcare is submitting this Special 510(k) to address modifications to the predicate Ultrasound Tracker [K121498]. The proposed Ultrasound Tracker was redesigned to withstand cleaning and disinfection associated with reuse in accordance with the following standards:

- AAMI TIR12:2010 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.
- AAMI TIR30:2011 – A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- ISO 17664:2004 – Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices.

- ANSI ST81:2004/(R) 2010 - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

VIII. Indications for Use

PercuNav is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Rotational Fluoroscopy, Endoscopy, and other imaging systems. CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, such as CT with MR, MR with ultrasound, etc. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account patient movement. This is intended for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

The device is intended to be used in interventional and diagnostic procedures in a clinical setting. The device is also intended for use in clinical interventions to determine the proximity of one device relative to another.

Example procedures include, but are not limited to:

- Image fusion for diagnostic clinical examinations and procedures
- Soft tissue biopsies (liver, lung, kidney, breast, pancreas, bladder, adrenal glands, lymph node, mesentery, etc.)
- Soft tissue ablation (liver, kidney, breast, pancreas, lung, etc.)
- Bone ablations
- Bone biopsies
- Nerve Blocks & Pain Management
- Drainage placements
- Hydrodissections
- Bladder Stimulation
- Fiducial placements
- Tumor resections
- Sinus procedures
- Intranasal procedures
- Transphenoidal procedures

IX. Substantial Equivalence

The technological characteristics of the proposed Philips PercuNav Ultrasound Tracker is equivalent to the cleared predicated device with the exception that this new tracker is provided non–sterile and intended undergo cleaning and disinfection reprocessing at the hospital facility.

This update to the Philips PercuNav Ultrasound Tracker is substantially equivalent to the FDA cleared frameless stereotaxic system, predicate PercuNav K121498. As required by risk analysis, all verification and validation activities were performed by designated individual(s) and the results demonstrated substantial equivalence.

The device labeling contains instructions for use which is substantially equivalent to the predicate device but has been revised in accordance with the *FDA Draft guidance Document Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on May 2, 2011* to ensure safety and effectiveness of the reprocessing instructions provided to the user.

X. Non Clinical Performance Data

Testing for the Philips PercuNav Ultrasound Tracker was performed to ensure that functional requirements have been met, and that core functions execute as expected. Safety and Effectiveness has been established through bench testing and non-clinical performance testing inducing Surgical Simulation and the Clinical Accuracy simulation tests. Results from performance testing conducted demonstrate that the Philips PercuNav Ultrasound Tracker is safe and effective for use with the PercuNav System [K121498].

Product requirements are decomposed into test cases and variations, consisting of conditions and expected results. Each case set is associated with a specific requirement and is grouped according to functional characteristics. The Verification and Validation plan identifies all variations, including input and expected results (outputs), test setup conditions (environmental needs), requirements, variations tested, and procedural steps taken to execute the test case. The Verification and Validation results summary demonstrate that the device satisfies all performance and functional requirements.

Surgical simulation
A real-world simulation of a guided surgical procedure to determine the accuracy of the PercuNav system using a control measurement gauge. It is also used to determine if the system works as intended in a simulated surgical environment. The system is validated using a phantom based simulation that is designed to determine the error in the system by determining a value of "Euclidian System Error". The Euclidian System Error is the "Target Registration Error" (TRE) commonly used for accuracy assessment in image guided surgery. All instrumentation and accessories provided with the PercuNav system are subjected to Surgical Simulation Test Case Protocol.

Non Clinical Accuracy
The Non Clinical Accuracy test is a simulation test intended to evaluate Image Registration and Image Fusion accuracy of the Philips PercuNav Ultrasound Tracker in order to demonstrate safety and effectiveness of the system.

a) Registration Test
The system performs spatial mapping from image space to physical space through a process called Registration. This allows the physician to correlate

image datasets with one another, as well as to the patient. The purpose of this test is to verify image registration

b) Image Fusion Accuracy Test

Image fusion provides the advantage of combining high resolution cross-sectional imaging modalities with live ultrasound imaging. Image fusion displays the pre-procedure images, reformatted in real time, to continuously match live ultrasound imaging. An electromagnetic tracker affixed to the ultrasound transducer tracks the position and orientation of the ultrasound scan plane. The PercuNav software uses this information to fuse the pre-procedure images and the live ultrasound into one image. The purpose of this test is to qualify each registration method that is available to the operator.

System testing to date shows that all accuracy and performance requirements for PercuNav system use with the Philips PercuNav Ultrasound Tracker have been met and the system is safe and effective for its intended use. The completed tests were conducted to ensure that the changes to the proposed device did not introduce any new issues of safety or effectiveness from our legally marketed device - K121498.

XI. Conclusion

Verification and Validation testing activities were required to establish the performance, functionality, and reliability characteristics of the modified Philips PercuNav Ultrasound Tracker. Testing involved system level tests, performance tests, and safety testing. Results of the verification and validation activities for the Ultrasound Tracker confirms that the device performed as intended, is safe and effective, and is substantially equivalent to the currently marketed device [K121498].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2013

Philips Healthcare
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K132087
Trade/Device Name: PercuNav System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, IYO, LLZ
Dated: July 1, 2013
Received: July 12, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

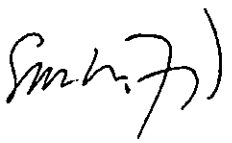
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132087

Device Name: PercuNav

Indications for Use:

PercuNav is a stereotaxic accessory for Computed Tomography (CT), Magnetic Resonance, (MR), Ultrasound (US), Positron Emission Tomography (PET), Single Photon Emission Computed Tomography (SPECT), Rotational Fluoroscopy, Endoscopy and other imaging systems. CT, Ultrasound, PET, MR, and Rotational Fluoroscopy may be fused in various combinations, such as CT with MR, MR with ultrasound, etc. It may include instrumentation to display the simulated image of a tracked insertion tool such as a biopsy needle, guidewire or probe on a computer monitor screen that shows images of the target organs and the current and the projected future path of the interventional instrument taking into account patient movement. This is intended for treatment planning and guidance for clinical, interventional, and/or diagnostic procedures. The device also supports an image-free mode in which the proximity of the interventional device is displayed relative to another device.

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Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Indications for Use

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- Soft tissue ablation (liver, kidney, breast, pancreas lung, etc.)
- Bone ablations
- Bone biopsies
- Nerve Blocks & Pain Management
- Drainage placements
- Hydrodissections
- Bladder Stimulation
- Fiducial placements
- Tumor resections
- Sinus procedures
- Intranasal procedures
- Transphenoidal procedures

Prescription Use ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132087